UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/682,460	10/08/2003	Kenneth E. Kadziauskas	27564	1644

7590 06/07/2007

Peter J. Gluck
Advanced Medical Optics, Inc.
1700 E. St. Andrew Place
Santa Ana, CA 92777-5162

EXAMINER	
HAND, MELANIE JO	

ART UNIT	PAPER NUMBER
3761	

MAIL DATE	DELIVERY MODE
06/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

c

Office Action Summary	**Application No.** 10/682,460	**Applicant(s)** KADZIAUSKAS ET AL.
	Examiner Melanie J. Hand	**Art Unit** 3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) *6,8,12,13,19,21,25-28,34,36 and 40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7,9-11,14-18,20,22-24,29-33,35,37-39,41-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-5, 7, 9-11, 14-18, 20, 22-24, 29-33, 35, 37-39 and 41-44 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-5, 7, 9, 14-18, 20, 22, 29-33, 35 and 41-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baerveldt et al (U.S. Patent No. 6,979,326) in view of Falk et al (5,797,733).

With respect to **claim 1:** Baerveldt teaches an infusion source for ocular surgery having a needle 1400 with at least an irrigation lumen 1622 comprising: a fluid supply 1480; an irrigation line interconnecting said fluid supply 1480 and said irrigation lumen 1622 (Fig. 13); and a tubular member 1410 disposed in fluid communication with said irrigation line and said irrigation lumen 1622, said tubular member 1410 having an expandable wall for enabling accumulation of fluid within said tubular member 1410, during occlusion of an aspiration lumen (lumen 1622 when said tubular member 1410 is expanding for permitting removal of material from a surgical site, i.e. when lumen 1622 is not being used for irrigation) and enhanced flow of fluid into said irrigation lumen 1622 upon clearing of the occlusion, i.e. when expansion of member 1410, and thus aspiration of material, stops. (Col. 11, lines 18-26, 34-37, 57-61)

Baerveldt does not teach a tubular member disposed along said irrigation line. Falk teaches an electromagnetic fluid pump for use in combination with a catheter for delivery to an infusion site. Falk teaches tubular member 436 disposed along an irrigation line and in fluid communication with irrigation lumen 440. Tubular member 436 has an expandable wall configured to expand upon accumulation of fluid within said tubular member 436 which can occur during the occlusion of an aspiration lumen such as that taught by Baerveldt and enhanced flow of fluid into irrigation lumen 440 upon clearing of the occlusion. Falk teaches that the accumulator in the fluid flow path between the pump outlet and catheter 440 alleviates inertial and viscous effects arising from the catheter, therefore it would be obvious to one of ordinary skill in the art to modify the device of Baerveldt so as to have a tubular member disposed along the irrigation line and in fluid communication with said irrigation line and said irrigation lumen as taught by Falk to alleviate inertial and viscous effects arising from the catheter.

With respect to **claim 2:** Tubular member 1410 is disposed proximate a handpiece 1405 effective for use in a phacoemulsification procedure. (Col. 11, lines 39-41)

With respect to **claim 3:** Tubular member 1410 is disposed in parallel fluid communication with said irrigation line and irrigation lumen 1622 (Figs. 14,16) (Col. 11, lines 18-21,31-35)

With respect to **claim 4:** The tubular member walls of member 436 taught by Falk are formed from silicone rubber, considered herein to be an elastic material, since the walls resume their initial size upon release of the accumulated fluid. The motivation to combine the teachings of Baerveldt and Falk are stated *supra* with respect to claim 1.

With respect to **claim 5:** Tubular member 1410 comprises a sheath disposed around the expandable wall. (Col. 10, lines 58-63)

With respect to **claim 7:** Baerveldt teaches that the sheath is comprised of electrically insulating material, substantially all of which materials (e.g. rubber, polyurethane foam) are flexible. (Col. 10, lines 58-62)

With respect to **claim 9:** The sheath and expandable wall are integrally molded. (Col. 9, lines 57,58, Col. 10, lines 58-62)

With respect to **claim 14:** Baerveldt teaches an infusion source for ocular surgery, said infusion source comprising: a handpiece having a needle with an irrigation lumen 2222 and an aspiration lumen 2224; a fluid supply in the form of an irrigation pump; an irrigation line interconnecting said fluid supply and said irrigation lumen 2222; and a tubular member 2100 disposed in fluid communication with said irrigation line and said irrigation lumen 2222, said tubular member 2100 having an expandable wall for enabling accumulation of fluid within said tubular member during occlusion of said aspiration lumen and enhanced flow of fluid into said irrigation lumen upon clearing of the occlusion. (Figs. 21,22) (Col. 11, lines 36-62, Col. 15, lines 4-20)

Baerveldt does not teach a tubular member disposed along said irrigation line. Falk teaches an electromagnetic fluid pump for use in combination with a catheter for delivery to an infusion site. Falk teaches tubular member 436 disposed along an irrigation line and in fluid communication with irrigation lumen 440. Tubular member 436 has an expandable wall configured to expand upon accumulation of fluid within said tubular member 436 which can occur during the occlusion of an aspiration lumen such as that taught by Baerveldt and enhanced flow of fluid into irrigation lumen 440 upon clearing of the occlusion. Falk teaches that the accumulator in the fluid flow path between the pump outlet and catheter 440 alleviates inertial and viscous effects arising from the catheter, therefore it would be obvious to one of ordinary skill in the art to modify the device of Baerveldt so as to have a tubular member disposed along the irrigation line and in fluid communication with said irrigation line and said irrigation lumen as taught by Falk to alleviate inertial and viscous effects arising from the catheter.

With respect to **claim 15:** Tubular member 2100 is disposed proximate the handpiece. (Fig. 21)

With respect to **claim 16:** Tubular member 2100 is disposed in parallel fluid communication with said irrigation line and said irrigation lumen 2222. (Figs. 21,22)(Col. 15, lines 4-20)

With respect to **claim 17:** The tubular member walls of member 436 taught by Falk are formed from silicone rubber, considered herein to be an elastic material, since the walls resume their initial size upon release of the accumulated fluid. The motivation to combine the teachings of Baerveldt and Falk are stated *supra* with respect to claim 14.

With respect to **claim 18:** The tubular member 2100 comprises a sheath 2146 disposed around the expandable wall. (Col. 14, lines 46-53)

With respect to **claim 20:** Baerveldt teaches sheaths comprised of electrically conductive material, substantially all of which materials (e.g. rubber, polyurethane foam) are flexible. (Col. 10, lines 58-62)

With respect to **claim 22:** The sheath 2146 and expandable wall are integrally molded. (Col. 14, lines 49,50)

With respect to **claim 29:** Baerveldt teaches an ocular surgical system for performing ocular surgery on an eye, comprising: a handpiece driven by a controller through a power line; an irrigation lumen 2222 and an aspiration lumen 2224, said infusion source comprising: a fluid supply in the form of an irrigation pump; an irrigation line interconnecting said fluid supply and said irrigation lumen 2222; and a tubular member 2100 disposed in fluid communication with said irrigation line and said irrigation lumen 2222, said tubular member 2100 having an expandable wall for enabling accumulation of fluid within said tubular member, during occlusion of said aspiration lumen 2224, and enhanced flow of fluid into said irrigation lumen upon clearing of the occlusion. (Figs. 21,22)(Col. 11, lines 36-62, Col. 15, lines 4-20)

Baerveldt does not teach a tubular member disposed along said irrigation line. Falk teaches an electromagnetic fluid pump for use in combination with a catheter for delivery to an infusion site. Falk teaches tubular member 436 disposed along an irrigation line and in fluid communication with irrigation lumen 440. Tubular member 436 has an expandable wall configured to expand upon accumulation of fluid within said tubular member 436 which can occur during the occlusion of an aspiration lumen such as that taught by Baerveldt and enhanced flow of fluid into irrigation lumen 440 upon clearing of the occlusion. Falk teaches that the accumulator in the fluid flow path between the pump outlet and catheter 440 alleviates inertial and viscous effects arising from the catheter, therefore it would be obvious to one of ordinary skill in the art to modify the device of Baerveldt so as to have a tubular member disposed along the irrigation line and in fluid communication with said irrigation line and said irrigation lumen as taught by Falk to alleviate inertial and viscous effects arising from the catheter.

With respect to **claim 30:** Tubular member 2100 is disposed proximate the handpiece. (Fig. 21)

With respect to **claim 31:** Tubular member 2100 is disposed in parallel fluid communication with said irrigation line and said irrigation lumen 2222. (Figs. 21,22)(Col. 15, lines 4-20)

With respect to **claim 32:** The tubular member walls of member 436 taught by Falk are formed from silicone rubber, considered herein to be an elastic material, since the walls resume their initial size upon release of the accumulated fluid. The motivation to combine the teachings of Baerveldt and Falk are stated *supra* with respect to claim 29.

With respect to **claim 33:** The tubular member 2100 comprises a sheath 2146 disposed around the expandable wall. (Col..14, lines 46-53)

With respect to **claim 35:** Baerveldt teaches sheaths, including sheath 2146, that are comprised of electrically conductive material, substantially all of which materials (e.g. rubber, polyurethane foam) are flexible. (Col. 10, lines 58-62)

With respect to **claim 41:** An accumulator for an ocular surgical handpiece, comprising: a tubular portion 2100 comprising an expandable wall; and a sheath 2146 disposed around the expandable wall; the accumulator configured to enable accumulation of fluid within the tubular member during occlusion of an aspiration lumen and to enhance the flow of fluid into an ocular surgical handpiece upon clearing of the occlusion. (Figs. 21,22)(Col. 11, lines 36-62, Col. 15, lines 4-20)

With respect to **claim 42:** The sheath 2146 and the expandable wall are integrally molded.(Col. 14, lines 49,50)

With respect to **claim 43:** Baerveldt teaches an infusion source for an ocular surgical handpiece, comprising: an irrigation fluid supply in the form of a pump; an irrigation line connected to the irrigation fluid supply for supplying fluid to an ocular surgical handpiece; an accumulator 2100 in fluid communication with the irrigation line, comprising: an expandable wall for enabling accumulation of fluid; and a sheath 2146 disposed around the expandable wall; the accumulator 2100 configured to provide accumulation of fluid within a tubular member during occlusion of an aspiration lumen and to enhance the flow of fluid into the ocular surgical handpiece upon clearing of the occlusion. (Figs. 21,22)(Col. 11, lines 36-62, Col. 15, lines 4-20)

With respect to **claim 44:** The sheath 2146 and the expandable wall are integrally molded. (Col. 14, lines 49,50)

Claims 10, 11, 22, 24, 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baerveldt et al (U.S. Patent No. 6,979,326) in view of Falk et al (5,797,733) as applied to claims 1-5, 7, 9, 14-18, 20, 22, 29-33, 35 and 41-44 above, and further in view of Sussman et al (U.S. Patent No. 6,589,201).

With respect to **claims 10,22,38:** The combined teaching of Baerveldt and Falk teaches that tubular member 2100 has expandable walls and a sheath 2146 but does not teach a plurality of expandable walls in spaced apart relation within a sheath. Sussman teaches a handpiece tip having coaxial irrigation and aspiration lumens that define an annular space therebetween. Surgical fluid is channeled through these lumens and expands within these tubes, thus expanding the tubes themselves. Sussman teaches that the fluid is pumped through the handpiece tip to the surgical site, thus when the irrigation lumen expands, occlusion of the aspiration lumen will occur. Sussman teaches that the tip allows internal heating of the surgical fluid to the desired temperature without the need for a separate heating device. Since Baerveldt teaches that the sonic energy applied to the said handpiece also provides heat to a fluid in the irrigation lumen of said handpiece, it would be obvious to one of ordinary skill in the art to substitute the handpiece tip of the combined teaching of Baerveldt and Falk with the handpiece taught by Sussman so as to effect a plurality of expanding walls with a spaced apart relation to provide heat to a surgical fluid as taught by Sussman without the need for a separate heating device. ('201, Col. 5, lines 9-18, Col. 2, lines 34-36)

With respect to **claim 11:** The combined teaching of Baerveldt and Falk and Sussman does not explicitly teach flexible elastic expanding walls defined by the walls of irrigation and aspiration tubes 115, but teaches that flexible tubes are known in the art, therefore it would be obvious to one of ordinary skill in the art to use flexible elastic material for the expanding walls with a reasonable expectation of success. ('201, Col. 1, lines 33-42)

With respect to **claim 24,39:** The combined teaching of Baerveldt and Falk teaches a handpiece effective for use during a phacoemulsification procedure, but does not teach a plurality of expandable walls. Sussman teaches a handpiece tip having coaxial irrigation and aspiration lumens that define an annular space therebetween. Surgical fluid is channeled through these lumens and expands within these tubes, thus expanding the tubes themselves. Sussman teaches that the tubes defining the expanding walls are comprised of flexible elastic material. Sussman teaches that the fluid is pumped through the handpiece tip to the surgical site, thus when the irrigation lumen expands, occlusion of the aspiration lumen will occur. Sussman teaches that the tip allows internal heating of the surgical fluid to the desired temperature without the need for a separate heating device. Since Baerveldt teaches that the sonic energy applied to the said handpiece also provides heat to a fluid in the irrigation lumen of said handpiece, it would be obvious to one of ordinary skill in the art to substitute the handpiece tip of the combined teaching of Baerveldt and Falk with the handpiece taught by Sussman so as to effect a plurality of expanding walls with a spaced apart relation to provide heat to a surgical fluid as taught by Sussman without the need for a separate heating device. The modified combined teaching of Baerveldt and Falk and Sussman teaches expandable walls and a sheath formed from an elastic material. Baerveldt teaches that the sheath is thick enough to be an effective electrical insulator, therefore the combined teaching of Baerveldt and Falk and Sussman teaches expandable walls that are thin, compared to the thickness of said sheath.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie J Hand
Examiner
Art Unit 3761

May 29, 2007

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER